K000784

MAY 1 8 2000

EXHIBIT #1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. Submitter's Identification:

Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46256

Date Summary Prepared:

March 6, 2000

2. Name of the Device:

The Cardiac Reader System

3. Predicate Device Information:

1. K#955868, Cardiac T Troponin T, Boehringer Mannheim Corp., Indianapolis, IN
2. K#972513, Tina-quant® Myoglobin Assay, Boehringer Mannheim Corp., Concord, MA

4. Device Description:

The Cardiac T quantitative and Cardiac M Tests, in conjunction with the Cardiac Reader Analyzer, are gold-labeled immunoassays for the rapid quantitative measurement of Troponin T and myoglobin respectively in human whole blood. The Cardiac Reader Analyzer measures the intensity of the signal line and converts it to a quantitative result.

The Cardiac Reader System allows rapid determination of the cardiac markers troponin T and myoglobin from a single whole blood sample. Quantitative results are available within minutes making it easier to choose the appropriate treatment.

Diagnosis of acute myocardial infarction (AMI) is generally based on the presence of at least two of three classic findings: clinical symptoms, diagnostic ECG, and serological findings of abnormal levels of total CK, LD or their isoenzymes. Often, due to the presence of clinical symptoms and changes in the ECG, the CK, CK-MB, LD and LDI serve primarily to confirm and monitor the course of the infarction. At other times, when chest pain is atypical, or ECG changes are non-diagnostic or absent, these markers provide important diagnostic information. Limitations to these serum marker include a

relatively narrow diagnostic window, difficulty in interpreting small increases and a lack of cardiac specificity. Troponin T can be an effective serum market whose cardiac specificity and wide diagnostic window makes it a valuable tool in the diagnosis of AMI, Troponin T has been shown to be elevated in all patients with AMI who are diagnosed by World Health Organization (WHO) criteria.

The measuring unit of the Cardiac reader contains a Charged Couple Device camera that optically reads the signal and the control line of the respective immunochemical test strips. The intensity of the signal line, determined by measuring its reflectance, is directly proportional to the concentration of the analyte. The test strip lot specific calibration curve is contained in a code chip. By its use the instrument converts the measured reflectance into a concentration.

The test requires a sample volume of 150ul heparinized venous blood and has a reaction time of 12 min for CardiacT Quantitative and 8 min for CardiacM.

The measuring range for the troponin T determination on the Cardiac reader is quantitative between 0.1 to 3 ug/L; between 0.05 and <0.1 µg/L "low", and below 0.05 µg/L "negative" is displayed. Above 3, "High" is displayed. The measuring range for CardiacM is 30 to 700 µg/L.

The Cardiac Reader System consists of the following components:

CARDIAC reader 902229	Desktop instrument for quantitative determination of myoglobin and troponin T with CARDIAC M and CARDIAC T Quantitative	Instrument plus dust cover, power adapter, power cable, and user manual
CARDIAC T Quantitative 1894307	Immunochemistry test strip for quantitative determination of cardiac troponin T using the CARDIAC reader	10 test (individually sealed) 1 code chip with calibration code 1 package insert
CARDIAC M 1893840	Immunochemistry test strip for quantitative determination of myoglobin using the CARDIAC reader	20 tests (individually sealed) 1 code chip with calibration code 1 package insert
CARDIAC control troponin T 1937553	Control solutions for use with CARDIAC T Quantitative	1 vial of negative control solution (lyophilized) for 6 determinations 1 vial with low troponin T concentrations (lyophilized) for 6 determinations
CARDIAC control myoglobin 1937545	Control solution for use with CARDIAC M	1 vial level 1 (lyophilzed) for 6 determinations 1 vial level 2 (lyophilzed) for 6 determinations
CARDIAC pipettes 1622889	For pipetting 150 µl sample from blood collection tubes (not sterile)	20 pipettes
Optional		
Printer 190317	Small thermal printer for CARDIAC reader	1 printer 1 roll of paper
Printer cable 1903225	Printer cable for serial port on the CARDIAC reader with power supply (no separate power supply required)	1 printer cable
Printer paper '903233	Thermal paper for printer 1903217	5 rolls

5. Intended Use:

The Cardiac T quantitative and Cardiac M Tests are intended for use with the Cardiac Reader Analyzer to provide rapid and quantitative measurement of cardiac Troponin T (cTnT) and Myoglobin in whole blood to aid in the detection of myocardial injuries. The analyzer and Cardiac Tests combine ease of use and rapid turnaround time with laboratory quality performance and reliability. With factory calibration and closed tube sampling, the system can be used in the central lab, STAT lab, emergency department, coronary care unit, chest pain center and other point of care locations.

6. Comparison to Predicate Devices:

a. Similarities and differences to predicate device:

Overall performance and characteristics of the CardiacM test on the Cardiac Reader System and the predicate device, the Tinaquant Myoglobin on Hitachi Systems, are summarized in the table below:

Parameter	CardiacM Test	Tina-quant Myoglobin
Intended Use	Test for the quantitative determination of human Myoglobin in -vitro	Test for the quantitative determination of human Myoglobin in-vitro
Analyte	Human Myoglobin	Human Myoglobin
Device	Immunological test strip	Immunoturbidimetric assay on Hitachi systems (704, 717, 911, 917)
Instrument required	Cardiac Reader	Hitachi systems (704, 717, 911, 917)
Principle of immunological reaction	Gold-labeled, optically read immuno sandwich assay	Latex-enhanced turbidimetric immunoassay
Antibodies	Mab 1: goldlabeled anti <myo> monoclonal antibody Mab 2: biotinylated anti <myo> monoclonal antibody	Latex particles coated with anti-human myoglobin antibodies (rabbit)
Detection method	Detection of signal line remission by CCD photosensor	Turbidimetric measurement of antigen-antibody complex
Turn around time	Approx. 10 min	Approx 10 min
Reaction time	8 min	Approx 10 min
Measuring range	30-700 ng/ml	3-560 ng/ml (depending on the conc. of the highest standard)
Sample material	Heparinized venous blood	Serum, plasma treated with heparin or EDTA
Sample volume	150 µl	20µl (Hitachi 704)
Accuracy: Cardiac M versus Tina-quant Myoglobin	Y= 0.976* X +3.664	
Imprecision controls (day-to-day)	CV 8.3% (2.6-15.0)	CV 2.8% (0.0 - 6.2)
Quality control	Two Cardiac Controls are separately available	Two controls are contained in the kit

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Overall performance and characteristics of the Cardiac T Quantitative Test on the Cardiac Reader System and the predicate device, the Troponin T Test on ES Systems, are summarized in the table below:

Parameter	**CardiacT Quantitative Test**	**Trop T Enzymun Test**
Intended Use	Test for the quantitative determination of human cardiac Troponin T (hcTnT) in-vitro	Test for the quantitative determination of human cardiac Troponin T (hcTnT) in-vitro
Analyte	Human cardiac Troponin T	Human cardiac Troponin T
Device	Immunological test strip	ELISA on Lab system ES (series 300,600 and 700)
Instrument required	Cardiac Reader	ES Series (Enzmun)
Principle of immunological reaction	Gold-labeled, optically read immuno sandwich assay	sandwich assay
Antibodies	Mab 1: goldlabeled anti <hcTnt> monoclonal antibody; Mab 2: biotinylated anti <hcTnt> monoclonal antibody	Mab 1: POD-labeled <hcTnt> monoclonal antibody; Mab 2: Biotinylated anti <hcTNT> monoclonal Fab fragment
Detection method	Detection of signal line remission by CCD photosensor	Indicator reaction and measurement of absorbance (photometric)
Turn around time	Approx. 15 min	Approx 10 min
Reaction time	12 min	Approx 10 min
Measuring range	0.13ng/mL	Approx 0-15ng/mL
Sample material	Heparinized venous blood	Serum, plasma treated with heparin or citrate
Sample volume	150 µl	140 µl
Accuracy: Cardiac T Quant versus Enzymun TroponinT Test	Y + 1,093X - 0.006	
Imprecision controls (within series)	CV 17.8% (9.5-34.1) (blood and controls)	CV 6.1 (3.1-11.1)
Quality control	Two Cardiac Controls are separately available	Two controls are contained in the kit

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Technical Performance Documentation for Myoglobin and Troponin Include:

- Precision Records
- Influence of Temperature
- Influence of Humidity
- Influence of Sample Age
- Calibration
- Recovery of Control Samples
- Stability
- Assay Evaluation
- Electrical and EMC Testing

8. **Discussion of Clinical Tests Performed:**

A multicenter evaluation of the Cardiac Reader was conducted which showed that all analytical and handling product claims were fulfilled by the Cardiac Reader System.

9. **Conclusions:**

The Cardiac Reader System is an analytically reliable system which will extend the range of applications of the visual TROPT test in the quantitative assessment of cardiac risk, and the availability of CARDIAC M test will allow early AMI recognition and reperfusion control.

The Cardiac Reader System has the same intended use and similar technological characteristics as predicate devices. Moreover, bench testing contained in this submission and clinical testing supplied demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, The Cardiac Reader System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 8 2000

Ms. Susan D. Goldstein-Falk
Official Correspondent
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K000784
Trade Name: The Cardiac Reader System
Regulatory Class: II
Product Code: MMI
Dated: March 6, 2000
Received: March 10, 2000

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K000784

Device Name The Cardiac Reader System

Indications For Use:

The Cardiac T quantitative and Cardiac M Tests are intended for use with the Cardiac Reader Analyzer to provide rapid and quantitative measurement of cardiac Troponin T (cTnT) and Myoglobin in whole blood to aid in the detection of myocardial injuries. The analyzer and Cardiac Tests combine ease of use and rapid turnaround time with laboratory quality performance and reliability. With factory calibration and closed tube sampling, the system can be used in the central lab, STAT lab, emergency department, coronary care unit, chest pain center and other point of care locations.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000784

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** ____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**